K062389

SECTION 5. 510(K) SUMMARY OR 510(K) STATEMENT

AUG 2 1 2006

Submission Correspondent:	Emergo Group, Inc. 2519 McMullen Booth Road Suite 510-295 Clearwater, Florida 33761 Phone: (727) 797-4727 Fax: (727) 797-4757 Email: igordon@emergogroup.com Contact: Ian P. Gordon Sr. Vice President
Submission Sponsor:	Foundation Milling Center (FMC) 235 Aero Drive Buffalo, NY 14225 Phone: (716) 838-3838 Fax: (716) 839-8004 Email: jacob_oppenheimer@yahoo.com Contact: Jacob Oppenheimer Vice President, Product Development
Date summary prepared:	May 31, 2006
Device trade name:	Foundation Milling Center Z-Blocks
Device common name:	Z-Blocks
Device classification name:	Porcelain Powder for Clinical Use
Legally marketed devices to which the device is substantially equivalent:	K051705, IPS E. MAX CAED/IPS E.MAX ZIRCAD, Ivoclar Vivadent, Inc.
Description of the device:	This product is a ceramic block made out of ZrO_2 (Zirconia Oxide). There is a metal chuck glued on the end of the block that holds the block into the CAD/CAM machine. The block is milled into cores for teeth and then is fired in an oven to harden the ZrO_2. Then the core is layered with ceramic porcelain to make a finished tooth.
Intended use of the device:	This product is indicated for use as a substructure for porcelain fused to ceramic fixed dental restorations; namely crowns and bridges. Foundation Milling Center Z-Blocks are machined at the user facility using CAD/CAM technology.

Technological characteristics:	The technological characteristics between the predicate and proposed devices are identical. There is no difference in fundamental scientific technology. They are made from the same materials and have the same intended use.
Conclusions:	By definition, a device is substantially equivalent when the device has the same intended use and the same technological characteristics as the predicate device. There are no significant differences between the Foundation Milling Center Z-Blocks and the predicate devices and therefore, the Foundation Milling Center Z-Blocks to not raise any questions regarding safety and effectiveness. The Foundation Milling Center Z-Blocks, as designed, are as safe and effective as the predicate device, and the device is determined to be substantially equivalent to the referenced predicate devices currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 1 2006

Foundation Milling Centre
C/O Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services NA, Incorporated
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K062389
Trade/Device Name: Z-Block 20/19, Z-Block 40/19, Z-Block 55/19
Regulation Number: 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: August 15, 2006
Received: August 16, 2006

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4. INDICATIONS FOR USE STATEMENT

510(k) Number: K062389

Device Name: Z-Block 20/19, Z-Block 40/19, Z-Block 55/19

Indications for Use: This product is indicated for use as a substructure for Porcelain fused to ceramic fixed dental restorations; namely crowns and bridges. Foundation Milling Center Z-Blocks are machined using CAD/CAM technology.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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...n of Anesthesiology, General Hospital,
...on Control, Dental Devices
...Number K062389